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Section II

510(k) SUMMARY

K011281

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Date Prepared: April 25, 2001

Applicant Information:

Name: Intuitive Surgical, Inc.
Address: 1340 W. Middlefield Road
Mountain View, California 94043

Establishment Registration Number: 2955842

Contact Person: Michael Yramategui
Phone Number: (415) 237-7048
Facsimile Number: (415) 526-2060
E-mail: mike_yramategui@intusurg.com

Device Information:

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR §878.4400)

Trade Name: Intuitive Surgical™ Ultrasonic Shears

Common Name: Ultrasonic Surgical System

Predicate Devices:

Olympus SonoSurg System	Olympus Optical Corp	K972114

Device Description:

The subject device is an endoscopic instrument with a grasping end effector and integral ultrasonic probe. It is used with the Intuitive Surgical® Endoscopic Instrument Control System and the Olympus SonoSurg System and accessories. The ultrasonic probe incorporated into the subject device is the same as used with the predicate device, but adapted so that it can be used with the Intuitive Surgical® Endoscopic Instrument Control System . Essentially, the subject device replaces the handle of the predicate device so that the instrument can be articulated with Instrument Control System instead of being

held directly by the surgeon. The Olympus SonoSurg system includes an System and transducer that converts electrical energy to mechanical energy in the form of ultrasonic vibrations. The transducer couples the energy to an ultrasonic probe within the device. A portion of the probe protrudes through the distal end of the instrument, and the instrument end effector has an opposing jaw that is articulated by the surgeon using the Intuitive Surgical® Endoscopic Instrument Control system. Cutting and coagulation of tissue occurs when the Olympus SonoSurg generator is activated while the jaw is closed on tissue. The device and accessories are essentially identical in size and shape to the referenced predicate device, and represent standard embodiments of surgical tools modified for use with the Intuitive Surgical® Endoscopic Instrument Control System.

Intended Use:

The Intuitive Surgical® Ultrasonic Shears is designed to be used in conjunction with the da Vinci™ Surgical System for the incision and coagulation of soft tissue in endoscopic surgical procedures.

Comparison to Predicate Device:

The Intuitive Surgical® Ultrasonic Shears is essentially identical in terms of shape, size, function, activation, and intended use to the predicate Class II endoscopic instrument cited. The primary difference is that the surgeon manipulates and positions the subject device using the Intuitive Surgical® Endoscopic Instrument Control System while the predicate device is handheld.

***In Vitro* Test Data:**

Design analysis and comparison as well as *in vitro* testing confirm that basic functional characteristics are substantially equivalent to the predicate device cited.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical® Ultrasonic Shears has been shown to be substantially equivalent to a currently marketed predicate device.

Intuitive™ and Intuitive Surgical® is a registered trademark of Intuitive Surgical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2001

Mr. Michael Yramategui
Director, Regulatory and Quality Affairs
Intuitive Surgical, Inc.
1340 West Middlefield Road
Mountain View, California 94043

Re: K011281
Trade/Device Name: Intuitive Surgical™ Ultrasonic Shears
Regulation Number: 876.1500
Regulatory Class: II
Product Code: NAY, LFL
Dated: April 25, 2001
Received: April 27, 2001

Dear Mr. Yramategui:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011281

Device name: Intuitive Surgical™ Ultrasonic Shears

Indications for Use:

The Intuitive Surgical® Ultrasonic Shears is designed to be used in conjunction with the da Vinci™ Surgical System for the incision and coagulation of soft tissue in endoscopic surgical procedures.

PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-the Counter Use_____

(per 21 CFR §801.109) (Optional Format 1-2-96)

for (Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011281